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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,752	01/02/2002	Zhihua Qiu	UNI.20	1617

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary**Application No.**

10/039,752

Applicant(s)

QIU ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The response filed September 5, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-21 are pending and are examined on the merits.

The terminal disclaimer filed on September 5, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the '679 patent has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 1-21 are presented for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),

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the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qui et al (U.S. Pat. 6,346,679) or Qiu et al (U.S. Pat. 6,133,440) in view of Hansen et al (U.S. Pat. 5,254,174) or DeFrees (U.S. Pat. 6,454,946).

Each of '679 and '440 disclose the precise process recited in applicant's claims, with the exception of the nanofiltration step recited as step (e). However, each of Hansen and DeFrees discloses that at the time of applicant's invention it was known to be advantageous to treat polysaccharide-containing compositions of the type disclosed in the '679 and '440 patents by nanofiltration, so as to remove impurities therefrom. See Hansen at column 8, lines 23-25. ("Nanofiltration also results in the removal of low molecular weight proteins and amino acids, so that the purity of the inulide mixture is improved.") See also DeFrees, at abstract. ("The carbohydrates are purified away from undesired contaminants such as compounds present in reaction mixtures following enzymatic synthesis or degradation of oligosaccharides.")

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(As an aside, note that Hansen and Defrees are applied in the alternative, not to supplement any shortcoming in either reference. Similarly the '679 and '440 patents are applied alternatively.)

The artisan of ordinary skill, recognizing from Hansen or DeFrees the advantages of using nanofiltration to improve the purity of the pharmaceutical product made according to the methods disclosed in the '679 and '440 patents, clearly would have been motivated to have added a nanofiltration step to the processes in the '679 and '440 patents. That is, based on the disclosures of either Hansen or DeFrees, the artisan of ordinary skill would have reasonably expected to have improved the properties of the product made by the process of the '679 and '440 patent, and therefore would have been motivated by Hansen/DeFrees to have added a nanofiltration step to the process disclosed in the '679 and '440 patents. A holding of obviousness is therefore required.

It is noted that applicant claims priority to the applications which matured into the '440 and '679 patents. However, the effective filing date of the subject matter in claims 1-21 of the instant application is January 2, 2002, which is more than 1 year after the October 17, 2000, issue date of the '440 patent. The '440 patent is therefore clearly

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applicable as prior art to claims 1-21, despite the priority claim to the application which matured into the '440 patent. The '679 patent is applicable to the present claims under 35 U.S.C. 102(e), because the '679 patent is a patent "to another" under that statute, since the instant case has a different inventive entity than the '679 patent.

All of applicant's argument regarding the remaining ground of rejection has been fully considered but it not persuasive of error. Applicant may be able to "swear behind" the '679 patent via declaration because of that patent's filing date. However, as discussed above, the '440 patent has an issue date which is more than one year prior to applicant's filing of the subject matter presently claimed. Thus, not only is the '440 patent prior art to this application, the '440 patent is a statutory bar to the issuance of the subject matter recited in the claims under examination. See MPEP § 2133.01

It is noted, as argued by applicant, that the products purified by Hansen and DeFrees differ somewhat from the products produced in the '679 and '440 patents. However, both '679 and '440 disclose that the products produced therein may be subjected to filtration steps as purification measures. See, e.g., '440 at column 4, line 46 through column 5, line 2. Thus,

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the artisan of ordinary skill, recognizing from Hansen and DeFrees that nanofiltration was an advantageous technique for saccharide purification, clearly would have been motivated to have used nanofiltration in the filtration steps disclosed in the '679 and '440 patents.

It is also noted that many different techniques have been used to purify organic compounds. However, as evidenced by Hansen and DeFrees, at the time of applicant's invention it was known to be advantageous to treat oligosaccharide-containing or polysaccharide-containing compositions of the type disclosed in the '679 and '440 patents by nanofiltration, so as to remove impurities therefrom. In short, the '679 and '440 patents recite the production of a polysaccharide which must be purified. Each of Hansen and DeFrees demonstrate that the claimed technique of nanofiltration was uniquely suited to the purification of oligosaccharides and/or polysaccharides, exactly the category of molecule produced in the '440 and '679 patents. Thus, the disclosures of Hansen and DeFrees not only provide motivation, but a reasonable expectation that nanofiltration would have been a suitable method of removing impurities from the polysaccharide-containing compositions of the '679 and '440 patents.

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Lastly, applicant alludes to certain unexpected results with respect to the nanofiltration, as compared to alcohol precipitation, particularly with respect to larger batch size. However, applicant's claims do not recite a limitation with respect to batch size. Moreover, applicant does not point to those facts or data demonstrating the unexpected nature of the claimed process. Similarly it is unclear what data applicant is using as a basis for comparison to the claimed process. Thus, because the evidentiary basis for the assertion of unexpected results is not clear, it is not clear on the current record that any unexpected results come from the claimed process, or that the claims are commensurate in scope with such a showing.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

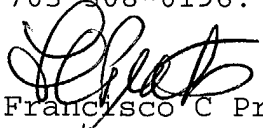
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expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
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FCP